UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

ERNEST PLEASANT,

Plaintiff

VS.

MERCK & CO., INC.

Defendant

PLAINTIFF CLAIMS

SUMMONS ISSUED TRIAL BY JURY LOCAL RULE 4.1 WAIVER FORM

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## **COMPLAINT**

#### **PARTIES**

- 1. The plaintiff Ernest Pleasant resides in Lynn, Essex County, Massachusetts.
- 2. At various points during and prior to 2002, the plaintiff took the drug Vioxx.
- 3. At all times relevant herein, defendant Merck & Co., Inc. (Merck), was and is an American pharmaceutical company incorporated under the laws of the State of New Jersey with its principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey. Defendant was and is in the business of profiting from the design, manufacture, marketing, distribution and/or sales of the brand-name prescription drug Vioxx (rofecoxib).
- 4. This court has subject matter jurisdiction pursuant to 28 U.S.C. §1332 (diversity jurisdiction) because the amount in controversy exceeds \$75,000.00 exclusive of interest and costs, and because this is an action by an individual plaintiff who is a citizen of a different state from the defendant.

#### FACTUAL ALLEGATIONS

5. This action arises from the sales and efficacy of Vioxx, a pain-relief drug containing rofecoxib. Vioxx is a selective COX-2 inhibitor marketed by defendant as an anti-inflammatory analgesic.

- 6. Defendant, Merck & Co., Inc. ("Merck") obtained FDA approval on Vioxx in approximately May of 1999 and began its distribution and sale throughout the United States in approximately May of 1999. Vioxx is a brand name used by Merck to market and distribute rofecoxib.
- 7. Defendant Merck distributed and sold Vioxx to consumers such as plaintiff. Vioxx was approved for marketing based on information in the New Drug Application, which was on a fast-track, 6-month approval process to FDA.
- 8. Despite knowledge in its clinical trials and post-marketing reports, studies and information relating to cardiovascular-related adverse health effects, defendant promoted and marketed Vioxx as safe and effective for persons such as plaintiff.
- 9. Defendant concealed the serious cardiovascular risks associated with Vioxx because a successful launch of Vioxx was viewed as critical for Merck and safety concerns over hypertension, thrombosis, edema and/or cardiovascular events would have drastically impacted Merck's positioning in the market as compared to its competition drug, Celebrex (celecoxib), which had been placed into the market by Merck competitors Pharmacia and Pfizer some 3 months prior to the launch of Vioxx.
- 10. Merck knowingly chose to market this product, despite its knowledge at product launch and in post-marketing data thereafter that use of Vioxx carried significant risk factors. These adverse effects were realized in adverse event reports, in clinical trials where such events were adjudicated by primary investigators with Merck's assistance, and in one or more studies shortly after market launch which showed statistically significant increases in adverse cardiovascular events among Vioxx users.
- 11. In industry sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck is a member and corporate sponsor, in June of 2000, it was shown that Vioxx use resulted in a statistically significant increase in hypertension and myocardial infarction. Merck did nothing to publish these studies, which were again reported and denied by Merck as to the hypertension problems in the official publication of the American Pharmaceutical Association, Pharmacy Today, Spin War Aside, Lessons Emerge From COX-2 Trials, in August 2000, Page 3).
- 12. Merck continued to deny the ill health effects associated with Vioxx while at the same time reaping the profits obtained through the non-disclosure. Merck engaged in an aggressive and expansive advertising and sampling program and gained continued increases in market share, which enhanced Merck's financial stability to the detriment of its consumers. The resultant effect to Merck in concealing and failing to reveal and warn of the risks was a more than \$2 billion profit in 2000 alone to Merck and an approximately 23 percent share of the market.

- 13. The profits to Merck were realized as it continued to withhold relevant data from plaintiffs and the health care industry generally. For example, in November of 2000, Merck caused the publication of a study in the New England Journal of Medicine and knowingly downplayed and/or withheld from this publication the severity of cardiovascular risks associated with Vioxx consumption over naproxen consumption.
- 14. On or about August 29, 2001, the Journal of The American Medical Association publihed a peer-reviewed human epidemiologic study by the Cleveland Clinic Foundation, Cleveland, Ohio, Dr. D. Mukherjee, et al., showing what Merck had concealed --that the relative risk of developing a "confirmed adjudicated thrombotic cardiovascular event" (defined in the article as "myocardial infarction, unstable angina, cardiac thrombus, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke, and transient ischemic attacks") among Vioxx users in Merck's trials at a 95% confidence interval ranged from 2.2 for event-free survival analysis, 2.38 compared to naproxen users, and 4.89 for developing serious cardiovascular events among aspirinindicated patients. See Mukherjee, D., et al., Risk of Cardiovascular Events Associated With Selective Cox-2 Inhibitors, JAMA. 286:8, 954-959, Aug. 22/29, 2001. In addition, the annualized myocardial infarction rates for Vioxx users compared to placebo revealed a statistically significant increase among Vioxx users. Id.
- 15. In the JAMA study the authors set forth the theory that "by decreasing PG12 production [Vioxx] may tip the natural balance between prothrombotic thromboxane A2 and antithrombotic PG12, potentially leading to an increase in thrombotic cardiovascular events." *Id.* at 957. In a follow-up peer-reviewed study reported in the Journal Of The American College of Cardiology on or about February 6, 2002, Dr. Richard J. Bing conducted scientific testing and confirmed that the Cox-2 inhibitor "tips the balance of prostacyclin/thromboxane in favor of thromboxane, leading to increased vascular and thrombotic events." Bing, R. & Lomnicka, M., *Why Do Cyclo-Oxygenase-2 Inhibitors Cause Cardiovascular Events*", J.A.C.C., 39:3, Feb. 6, 2002. This biological plausibility is further supported by studies completed at the University of Pennsylvania. Cheng, Y., et al, *Role of Prostacyclin in the Cardiovascular Response to Thromboxane* A2, Journal of Science, V.296:539-541, Apr. 19, 2002.
- 16. In responsive Merck-authored and sponsored reviews, Merck set forth the theory that naproxen had a cardioprotective effect and therefore accounted for the cardiovascular risks among its Vioxx users. However, this theory was debunked in approximately January of 2002, by a Vanderbilt University School of Medicine human epidemiologic peer-reviewed study publihed in The Lancet, concluding that based upon information previously available there is an absence of a protective effect of naproxen or other non-aspirin non-steroidal anti-inflammatory drugs on risk of coronary heart disease. Ray, W., et al., Non-Steroidal Anti-

- inflammatory Drugs and Risk of Serious Coronary Heart Disease: An Observational Cohort Study, The Lancet, 359:118-123, Jan. 12, 2002.
- In mid-September, 2001, Merck received a third Warning Letter from FDA 17. stating in part that Defendant's promotional activities and materials are "false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug and Cosmetic Act (the Act) and applicable regulations." The FDA stated that defendant's promotional campaign "minimizes the potentially serious cardiovascular findings" from a Vioxx study and "misrepresents the safety profile for Vioxx." As to Merck's May 22, 2001 press release, the FDA wrote "your claim in the press release that Vioxx has a 'favorable safety profile' is simply incomprehensible, given the rate of MI [myocardial infarction] and serious cardiovascular events compared to naproxen. The implication that Vioxx's cardiovascular profile is superior to other NSAIDs is misleading: in fact, serious cardiovascular events were twice as frequent in the Vioxx treatment group ... as in the naproxen treatment group...."
- In approximately April of 2002, Merck was required to place cardiovascular 18. warnings on its Vioxx labeling based on the results of the VIGOR study. In addition, Merck was required to place new label warnings relaying that Vioxx 50 mg per day is not recommended for chronic use. These warnings were based on information that had been in Merck's possession by approximately January of 2000 at the latest and, as such, Merck did not meet its obligation to provide adequate "direction or warnings" as to the use of Vioxx. Neither did Merck fulfill its alleged obligation to warn the prescribing health care provider of these risks.
- 19. On September 30, 2004, Vioxx was withdrawn from the market worldwide when the data safety monitoring board overseeing a long-term study of Vioxx recommended that the study be halted because of an increase risk of serious cardiovascular events, including heart attacks and strokes, among patients taking Vioxx.
- 20. At all times relevant to this litigation, defendant Merck had a significant market share based upon claims of Vioxx's efficacy, a very aggressive marketing program which included financial incentives to sales teams, infusion of some 700 new sales representatives, and a massive direct-to-consumer advertising and physician sampling program.
- As a result of such marketing, Vioxx gained a significant market share in 21. competition with Celebrex that Merck would not have gained if Merck had not suppressed information about Vioxx and/or made false representations of Vioxx's superiority and efficacy.
- 22. If defendant had not engaged in this conduct, prescribers such as plaintiff's prescriber would not have prescribed Vioxx and patients, such as the plaintiff,

- would have switched from Vioxx to safer products or would have refrained wholly from any use of Vioxx.
- From approximately 1999 through present, defendant continued to engage in a 23. common scheme in marketing, distributing and/or selling Vioxx under the guise that it was safe and efficacious for persons such as plaintiff.
- 24. Plaintiff alleges that the suppression of this information constituted a common scheme by defendant to conceal material information from plaintiff.
- 25. Plaintiff alleges that the marketing strategies, including without limitation the detail and sampling programs and direct-to-consumer advertising, of the defendant targeted plaintiff to induce plaintiff to purchase Vioxx. At the time the defendant distributed, manufactured and marketed Vioxx, defendant intended that plaintiff would rely on the marketing, advertisements and product information propounded by defendant.
- The actions of defendant, in failing to warn of the clear and present danger posed 26. to others by the use of its drug, Vioxx, in suppressing evidence relating to this danger, and in making deliberate and misleading misrepresentations of fact to minimize the danger or to mislead prescribers and patients as to the true risk, constitutes such clear, blatant and outrageous conduct.

## **COUNT 1: NEGLIGENCE**

- 27. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.
- 28. Defendant, directly or indirectly, negligently manufactured, designed, tested, labeled, packaged, distributed, promoted, marketed, advertised or sold Vioxx (rofecoxib) in the stream of commerce, when the defendant knew, or in the exercise of ordinary care, should have known that Vioxx posed a significant risk to plaintiff's health and well being, which risk was not known to plaintiff or her prescriber.
- 29. At all times material hereto, defendant had a duty to plaintiff to exercise reasonable care in the design, testing, labeling, packaging, distribution, promotion, marketing, advertisement, sampling or sale of Vioxx (rofecoxib).
- 30. Defendant breached its duty and was negligent in its actions, misrepresentations, and omissions toward plaintiff in that the defendant:

- a. Failed to include adequate warnings with the medications that would alert plaintiff and other consumers to the potential risks and serious side effects of Vioxx ingestion;
- b. Failed to include adequate information or warnings with the medication that would alert plaintiff and the health care community to refrain from use of Vioxx without first prescribing traditional NSAIDs such as naproxen or ibuprofen;
- c. Failed to adequately and properly test Vioxx before and after placing it on the market;
- d. Failed to conduct sufficient testing on Vioxx which, if properly performed, would have shown that Vioxx had serious side effects, including, but not limited to the cardiovascular events described above;
- e. Failed to adequately warn plaintiff and her health care providers that use of Vioxx carried a risk of cardiovascular events, stroke and death; among other serious side effects;
- f. Failed to provide adequate post-marketing warnings or instructions after the defendant knew or should have known of the significant risks of personal injury and death as identified herein among other serious side effects from the use of Vioxx;
- g. Failed to adequately warn plaintiff that Vioxx should not be used in conjunction with any risk factors for these adverse effects such as a family history of ischemic heart disease, or risk factors for ischemic cardiovascular disease;
- h. Failed to adequately disclose and warn plaintiff that he undertook the risk of adverse events and death as described herein;
- i. Failed to adequately and timely inform the health care industry of the risks of serious personal injury and death from Vioxx ingestion as described herein.
- 31. Defendant knew or should have known that Vioxx caused unreasonably dangerous risks and serious side effects, including death, of which plaintiff would not be aware. Defendant Merck nevertheless advertised, marketed, sold and distributed the drug knowing that there were safer methods and products.
- 32. As a direct and proximate result of the negligence and breach of defendant, plaintiff sustained serious injury including but not limited to heart attack and catastrophic effects therefrom. Defendant owed a duty to plaintiff to use

reasonable care in its actions. Defendant's failure to use reasonable care proximately caused plaintiff's injuries.

### COUNT II: BREACH OF WARRANTY

- 33. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.
- 34. When defendant placed Vioxx into the stream of commerce, defendant knew of the use for which it was intended and expressly and impliedly warranted to plaintiff that use of Vioxx was a safe and acceptable means of treatment.
- 35. Plaintiff reasonably relied upon the expertise, skill, judgment and knowledge of the defendant and upon the express and/or implied warranty that Vioxx was of merchantable quality and fit for use as intended.
- 36. Vioxx was not of merchantable quality and was not safe or fit for its intended use because it was and continues to be unreasonably dangerous and unfit for the ordinary purposes for which it is used in that it caused injury to plaintiff. Merck breached the warranty because Vioxx was unduly dangerous in expected use and did cause undue injury to plaintiff.
- 37. Defendant breached the implied warranty of merchantability because Vioxx cannot pass without objection in the trade, is unsafe, not merchantable, and unfit for its ordinary use when sold, and is not adequately packaged and labeled.
- 38. Defendant expressly warranted to the market, including the plaintiff, by and through statements made by defendant or its authorized agents or sales representatives, orally and in publications, package inserts, and other written materials to the health care community, that Vioxx was safe, effective, fit and proper for its intended use.
- 39. In using Vioxx, plaintiff relied on the skill, judgment, representations, and foregoing express warranties of defendant. These warranties and representations provided to be false because the product was not safe and was unfit for the uses for which it was intended.
- 40. As a direct and proximate result of defendant's breach of warranties, plaintiff sustained serious and permanent injuries including but not limited to heart attack and catastrophic effects therefrom.

PLAINTIFF CLAIMS TRIAL BY JURY.

> The Plaintiff, By His Attorneys,

Edward M. Swartz BBO #489540 Alan L. Cantor BBO #072360 Swartz & Swartz 10 Marshall Street Boston, MA 02108

617-742-1900

# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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ATTORNEY'S NAME Alan L. Cantor, Esq./Edward M. Swartz, Esq.											
ADDRESS Swartz & Swartz, 10 Marshall St., Boston, MA 02108											
TELEPHONE NO. 617-742-1900											
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SJS 44 (Rev. 3/99)

## CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS		DEFENDANTS					
Ernest Pleasa	nt	Merck	& Co., Inc.	11 12 12 55			
	of First Listed Plaintiff <u>Essex County</u> CEPT IN U.S. PLAINTIFF CASES)	County of Residence of First Listed  (IN U.S. PLAINTEF CASES ONLY)  NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.					
(c) Attorney's (Firm Nam	ne, Address, and Telephone Number)	Attorneys (If Known)					
Swartz & Swar 10 Marshall S (617) 742-190	St., Boston, MA 02108						
II. BASIS OF JURISE	OICTION (Place an "X" in One Box Only)	ZENSHIP OF PRINCIPAL PARTIES(Place an "X" in One Box for Plaintiff versity Cases Only)  and One Box for De fendant)					
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110 Insurance   120 Marine   130 Miller Act   140 Negotiable Instrument   150 Recovery of Overpayment & Enforcement of   154 Recovery of Defauled Student Loans (Excl. Veterans)   153 Recovery of Overpayment of Veteran's Benefits   160 Stoc kholders' Suits   190 Other Contract   195 Contract Product Liability   REAL PROPERTY   210 Land Condemnation   220 Foreclosure   230 Rent Lease & Ejectment   240 Torts to Land   245 Tort Product Liability   290 All Other Real Property	Slander   368 Asbestos Pers Injury Product Liability   340 Marine   PERSONAL PROP   370 Other Fraud   370 Other Fraud   370 Other Fraud   370 Other Fraud   380 Other Persona   355 M otor V chicle   Product Liability   385 Property Dam   Product Liability   Side Marian   Product Liability   Side Marian   Product Liability   Side Marian   Side	y   621 tice   622 y   631 onal   640 t   651 t   661 t   691 tity   710 tity   721 TIONS   731 cate   740 Other   79	O Agriculture O Other Food & Drug D Other Food & Drug D Drug Related Seizure of Property 21 USC O Liquor Laws O R.R. & Truck O Airline Regs. O Occupational Safety/Health O Other  LABOR O Fair Labor Standards Act O Labor/M gmt. Relations O Labor/M gmt. Reporting & Disclosure Act O Railway Labor Act O Other Labor Litigation O Other Labor Litigation O Other Labor Litigation O Empl. Ret. Inc. Security Act	☐ 864 SSID Title XVI	400 State Reap portionment   410 Antitust   430 Banks and Banking   450 Commerce/ICC Rates/etc.   460 Deportation   470 Racke teer Influenced and Corrupt Organizations   810 Selective Service   850 Securities/Commodities/Exchange   875 Customer Challenge   12 USC 3410   891 Agricultural Acts   892 Economic Stabilization Act   893 Environmental Matters   894 Energy Alboation Act   895 Freedom of Information Act   9900 Appeal of Fee Determinational Determination   950 Constitutionality of State Statutes   890 Other Statutory Actions		
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VI. CAUSE OF ACTI	ON (Cite the U.S. Civil Statute under which you are Do not cite jurisdictional statutes unless divers		niel statement of cause.				
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VII. REQUESTED IN COMPLAINT:	UCHECK IF THIS IS A CLASS ACT UNDER F.R.C.P. 23	ION DEV	DEMAND \$ CHECK YES only if demanded in complaint:  JURY DEMAND: XX Yes  \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \				
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